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February 6, 2006

### VIA EFILING

The Hon. Kent A. Jordan  
USDC for the District of Delaware  
844 King Street  
Wilmington, DE 19801

### **RE: In Re: '318 Patent Infringement Litigation, C.A. No. 05-356 (KAJ) (consolidated)**

Your Honor:

My firm, along with Rakoczy Molino Mazzochi Siwik LLP, represent Defendants Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc. (collectively, "Mylan"), in the captioned consolidated litigation. On behalf of Mylan, we write in accordance with Section 4(f) of the Revised Scheduling Order (D.I. 81) and Your Honor's Civil Trial Procedures in response to Plaintiffs' letter of January 30, 2006, raising certain purported discovery disputes in connection with Mylan's document production, (D.I. 92). A telephone conference with the Court is scheduled for Tuesday, February 7, 2006, at 3:00 p.m. EST to discuss this matter. (D.I. 93).

Plaintiffs' January 30 letter claims that Mylan "has refused and/or failed to produce" documents in response to Plaintiffs' document production. Not so. As Mylan explained to Plaintiffs before they prematurely ran to the Court, Mylan has never taken such position. Indeed, Mylan continues to fully comply with its discovery obligations in this case. Plaintiffs' letter thus grossly mischaracterizes the current status of discovery.

Mylan received Plaintiffs' "meet and confer" letter on or about January 23, 2006. There, Plaintiffs raised the same purported discovery deficiencies that they currently raise with this Court. Plaintiffs concluded that letter by stating that "if our understanding of Mylan's position is incorrect and intends to produce promptly documents responsive to these requests, please let me know by no later than the close of business January 25." (D.I. 92, Ex. C at 3). Mylan promptly responded to Plaintiffs' letter. Among other things, Mylan not only pointed to the thousands of pages of highly responsive documents produced to date, but also explained that Mylan fully intended to continue satisfying its discovery obligations by producing "additional responsive, non-privileged documents within the course of the next week . . ." (*Id.*, Ex. D at 2). In light of Mylan's asserted intent and Plaintiffs' representation that any issues raised in their January 25 letter would be moot if Mylan produced additional responsive documents, Mylan reasonably concluded that no dispute existed at this time. Indeed, Mylan currently sees no real dispute, particularly given its two supplemental document productions. (See Exs. A and B hereto). Despite Mylan's efforts, Plaintiffs nevertheless filed their letter with the Court on January 30, having made no attempt to follow up with Mylan's counsel or to await production of the documents promised in Mylan's responsive letter.

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Plaintiffs' January 30 letter raises purported disputes over certain categories of documents. But as explained in Mylan's January 25 letter, (D.I. 92, Ex. D at 2), even a cursory review of the documents that Mylan had produced by that date demonstrates that Mylan has, in fact, produced documents responsive to these "disputed" categories. For example, in response to Plaintiffs' Request No. 3.d, Mylan has produced its entire ANDA, which is directly responsive to that Request that seeks documents relating to Mylan's ANDA for galantamine hydrobromide. With respect to Request No. 16, Plaintiffs already are in possession of Mylan's Notice of Paragraph IV Certification, and Mylan has produced all prior art cited in this Notice. Otherwise, Mylan sufficiently has addressed previous concerns raised by Plaintiffs in connection with Plaintiffs' discovery requests. For example, Mylan has advised on multiple occasions that based on Mylan's good faith and reasonable investigation to date, Mylan has no documents responsive to Request No. 20 seeking documents pertaining to the licensing of the '318 patent. To the extent that Mylan discovers any responsive, non-privileged documents during its further investigation, Mylan fully intends to comply with its discovery obligations by producing responsive, non-privileged documents as previously advised. Plaintiffs fail to explain how, by producing these documents or the documents in its supplemental productions, Mylan has failed and/or refused to produce responsive documents.<sup>1</sup>

Plaintiffs' claim that Mylan is being "evasive" when by promising to "produce all responsive, non-privileged documents relevant to the issues of infringement . . . and the invalidity of the '318 patent" also goes nowhere. Plaintiffs argue that they are entitled to discovery that is "relevant to the claim or defense of any party." With Defendants having agreed not to contest infringement, the only "claim" or "defense" currently at issue is invalidity. Mylan has responded that it intends to produce all responsive documents relevant to the issue of invalidity. And, in fact, Mylan has produced such documents based on Mylan's reasonable investigation to date. Again, Plaintiffs' argument fails to explain what dispute exists that this Court should decide. And for good reason – there is none.<sup>2</sup>

Although no current dispute exists, the fact is that Plaintiffs' discovery requests are overly broad in several material respects. For example, Plaintiffs seek "all documents" relating to "any" galantamine product or "any product intended to treat dementia of the Alzheimer's type." (D.I. 92, at 2). Plaintiffs never explain why "all" documents relating to "any" such product possibly could be relevant to invalidity. And, in fact, "all" such documents are not relevant, even to secondary considerations of non-obviousness.<sup>3</sup> At best, documents responsive to these requests that were created *before* January 15, 1985 (the critical date for the '318 patent) *might* be relevant to secondary considerations. But Plaintiffs have not so limited their

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<sup>1</sup> Mylan's supplemental productions included documents relating to Mylan's evaluation of the galantamine tablet market and Mylan's development of its galantamine tablet product; correspondence relating to Mylan's galantamine tablet ANDA; and amendments to Mylan's galantamine tablet ANDA. All are relevant to categories of documents over which Plaintiffs contend a "dispute" exists.

<sup>2</sup> Plaintiffs contend that Mylan should produce documents related to their willfulness claim because such documents also are related to the issue of invalidity. (D.I. 92, at 3). In addition to lacking any explanation or legal support, Plaintiffs' argument merely is an attempt to end run-around not only Mylan's pending motion to dismiss or bifurcate willfulness (D.I. 57-59, 76, 85), but the law as defined in the decision of *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), and by multiple district court decisions applying *Glaxo*.

<sup>3</sup> Plaintiffs' continued reliance on secondary considerations as a basis for obtaining discovery from Mylan and the other Defendants is puzzling given that, as discussed below, they have refused to provide discovery on this issue.

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discovery requests, seeking “all” documents irrespective of when created. Under the applicable case law, Plaintiffs have no right to “all” documents relating to “any” galantamine product or “any product intended to treat dementia of the Alzheimer’s type” because “all” such documents could not possibly be relevant to the pending invalidity issues. Again, Mylan has produced, and will continue to produce, non-privileged documents that are relevant to the invalidity defenses at issue here.

In the end, Plaintiffs’ complaint could only be the timing of Mylan’s production, and not its substance. If this is the case, Plaintiffs are in no position to lodge such a complaint. For example, Mylan’s First Set of Interrogatories to Plaintiffs – served over four months ago – seeks the identity of “the specific secondary considerations on which Janssen intends to rely” and “all documents supporting Janssen’s secondary consideration assertions.” (Ex. C hereto, at 7). Mylan’s First Set of Document Requests also sought specific categories of documents relating to the alleged commercial success of Razadyne®. (See, e.g., Ex. D hereto, at 8-14). Janssen refused to substantively respond to Mylan’s interrogatory, arguing that it is “premature.” (Ex. C hereto, at 8). Janssen also has failed to produce any documents relevant to this issue, even though they themselves concede before this Court that secondary considerations is an issue relevant to this litigation. (See D.I. 92, at 2). Plaintiffs’ failure to produce any documents or otherwise substantively respond to discovery requests related to commercial success or secondary considerations is especially egregious given Plaintiffs’ representation to the Court that commercial success is a secondary consideration upon which Plaintiffs intend to rely in response to the invalidity claims asserted by Defendants. (See D.I. 64, at 8). Thus, Plaintiffs’ complaint about the timing of Mylan’s production rings hollow.

Finally, the timing of Plaintiffs’ premature letter motion is suspect. Defendants issued subpoenas requiring key witnesses in this case, including the inventor and the attorneys that prosecuted the ‘318 patent, to appear for deposition in mid-January 2006. Defendants picked these dates in order to have sufficient time to assert additional defenses under the Court’s cut-off for pleading amendments. Conveniently for Plaintiffs, none of the witnesses that Defendants subpoenaed purportedly was available for deposition until the week of the current February 10 cut-off date. Just two days before Plaintiffs called the Court to schedule the February 7 hearing, counsel for Mylan informed Plaintiffs that Defendants would ask this Court to extend the pleading amendment cut-off date in light of Plaintiffs’ failure to present their witnesses on the dates in the subpoenas (Plaintiffs never moved for a protective order to change the dates) and their failure to offer dates that would give Defendants a reasonable amount of time to use the information learned from these depositions to formulate defenses such as unenforceability. While Plaintiffs ultimately agreed to extend the cut-off date, the timing of their decision to rush to the Court with this alleged discovery dispute is, again, suspect.

Defendant Mylan respectfully requests that the Court deny Plaintiffs’ request for relief. We look forward to speaking with Your Honor regarding these matters on February 7. Thank you for your consideration.

Respectfully,  
  
Mary B. Matterer

Attachments

cc: Attached Service List (via email)

SERVICE LIST

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<i>Counsel for Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.</i>	

*In re: ‘318 Patent Infringement Litigation,  
C.A. No. 05-356 (KAJ) (consolidated) (D. Del.)*

**EXHIBIT A  
to Mylan’s 2/6/06 Letter to Court:**

1/30/06 Mylan letter producing documents



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January 30, 2006

**VIA FedEx®**

Laura H. McNeill, Esq.  
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1201 Pennsylvania Avenue, NW  
Washington, D.C. 20004-2401

**Re: *In re: '318 Patent Litigation, Civil Action No. 05-356 (KAJ) (D. Del.)***

Dear Laura:

Enclosed please find one CD-ROM containing documents bearing bates numbers MYLAN(GAL) 02413-04731. The documents are produced in single page .tiff image format with associated cross-reference files.

Very truly yours,

RAKOCZY MOLINO MAZZOCHI SIWIK LLP

A handwritten signature in black ink, appearing to read "Lara Monroe Sampson".

Lara E. Monroe-Sampson

Enclosure (1 CD-ROM)  
cc (via Fed Ex®): Steven J. Balick, Esq. (w/out encl.)

*In re: ‘318 Patent Infringement Litigation,  
C.A. No. 05-356 (KAJ) (consolidated) (D. Del.)*

**EXHIBIT B  
to Mylan’s 2/6/06 Letter to Court:**

2/2/06 Mylan letter producing documents



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February 2, 2006

**VIA FedEx®**

Laura H. McNeill, Esq.  
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**Re: *In re: '318 Patent Litigation, Civil Action No. 05-356 (KAJ) (D. Del.)***

Dear Laura:

Enclosed please find one CD-ROM containing documents bearing bates numbers MYLAN(GAL) 04732-04897. The documents are produced in single page .tiff image format with associated cross-reference files.

Very truly yours,

RAKOCZY MOLINO MAZZOCHI SIWIK LLP

A handwritten signature in black ink that reads "Lara Monroe-Sampson".

Lara E. Monroe-Sampson

Enclosure (1 CD-ROM)  
cc (*via Fed Ex®*): Steven J. Balick, Esq. (w/out encl.)

*In re: ‘318 Patent Infringement Litigation,  
C.A. No. 05-356 (KAJ) (consolidated) (D. Del.)*

**EXHIBIT C  
to Mylan’s 2/6/06 Letter to Court:**

Plaintiffs’ Responses to Mylan’s  
First Set of Interrogatories

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

JANSSEN PHARMACEUTICA N.V.,	)	
JANSSEN, L.P., and	)	<b>CONFIDENTIAL PURSUANT TO</b>
SYNAPTECH, INC.,	)	<b>LOCAL RULE 26.2</b>
	)	
Plaintiffs/Counterclaim-Defendants,	)	Civ. Action No. 05-371 (KAJ)
	)	
v.	)	
	)	
MYLAN PHARMACEUTICALS INC.	)	
and MYLAN LABORATORIES INC.,	)	
	)	
Defendants/Counterclaim-Plaintiffs.	)	

**PLAINTIFFS JANSSEN PHARMACEUTICA N.V.'S, JANSSEN, L.P.'S, and  
SYNAPTECH, INC.'S OBJECTIONS AND RESPONSES TO DEFENDANTS MYLAN  
PHARMACEUTICALS INC.'S AND MYLAN LABORATORIES INC.'S  
FIRST SET OF INTERROGATORIES TO PLAINTIFFS (Nos. 1-6)**

Pursuant to Rule 33 of the Federal Rules of Civil Procedure, Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P., and Synpatech, Inc. (collectively, "Plaintiffs") object and respond to Defendants Mylan Pharmaceutical Inc.'s and Mylan Laboratories Inc.'s (collectively, "Mylan" or "Defendants") First Set of Interrogatories (Nos. 1-6) ("the interrogatories") as follows:

**General Objections**

A. Plaintiffs object to each of Defendants' interrogatories to the extent it seeks information that is (i) subject to the attorney-client privilege; (ii) subject to attorney work product immunity; and/or (iii) subject to any other privilege. Plaintiffs hereby claim such privileges and immunities to the extent implicated by each interrogatory, and exclude privileged and protected information from their responses. Any disclosure of such privileged or immunized information is inadvertent and is not intended to waive those privileges and immunities.

B. Plaintiffs object to the interrogatories on the grounds and to the extent that they call for the provision of information that is overbroad, unduly burdensome, and not relevant to the subject matter of the pending action or that is not reasonably calculated to lead to the discovery of admissible evidence.

C. Plaintiffs object to the interrogatories, and to the Instructions and Definitions therein, on the grounds and to the extent that they purport to impose any obligation on Plaintiffs that is beyond the scope of Rules 26 and 33 of the Federal Rules of Civil Procedure or other applicable law.

D. Plaintiffs' written responses and production of documents are based on information presently available to and located by Plaintiffs and their attorneys. As Plaintiffs have not completed their investigation of the facts relating to this case, their discovery in this action, or their preparation for trial, Plaintiffs' written responses and production of documents are made without prejudice to their right to supplement or amend their written responses and production of documents and to present evidence discovered hereafter at trial.

E. Plaintiffs object to the interrogatories to the extent that they purport to require disclosure or production of information subject to confidentiality requirements or expectations between Plaintiffs and any third party.

F. Plaintiffs' responses are provided without prejudice to Plaintiffs' right to oppose the admissibility or use of any document produced by Plaintiffs or any other party or third party in this case. Plaintiffs' production of a document in response to these interrogatories should not be taken as an admission concerning its authenticity, relevance, or admissibility. Further, any statement in these responses that Plaintiffs will produce any non-privileged responsive documents that are discovered in a reasonable search of files within their possession,

custody, or control should not be construed as an assertion that any such documents in fact exist; such a statement means only that Plaintiffs will conduct a reasonable, good-faith search for any such documents and will produce any non-privileged responsive documents that are found.

Plaintiffs reserve their right to require the return of any privileged document that may inadvertently be produced in response to these interrogatories. Plaintiffs also reserve the right to designate (or re-designate) any confidential document that may inadvertently be produced without the appropriate confidentiality designation.

G. Plaintiffs' objections and responses to the interrogatories, including any production of related documents, are not intended to waive or prejudice any objections Plaintiffs may assert now or in the future, including, without limitation, objections as to the relevance of the subject matter of any interrogatory or document request, or to the admissibility of any response or document or category of responses or documents at trial. Plaintiffs expressly reserve any and all rights and privileges under the Federal Rules of Civil Procedure, the Federal Rules of Evidence and any other law or rule, and the failure to assert such rights and privileges or the inadvertent disclosure by Plaintiffs of information protected by such rights or privileges shall not constitute a waiver thereof, either with respect to these responses or with respect to any future discovery responses or objections.

H. Plaintiffs object to the interrogatories to the extent that the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues.

I. Plaintiffs object to Defendants' definition of "you," "your," "Janssen," "Janssen Pharmaceutica N.V.," "Janssen, L.P.," and "Synaptech" as confusing, overly broad, and

unduly burdensome. For purposes of these interrogatories, “you” and “your” shall refer to Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc., named Plaintiffs to this litigation. “Janssen” shall refer to the named Plaintiffs, Janssen Pharmaceutica, N.V. or Janssen, L.P., either collectively or individually, as specified in each of Plaintiffs’ responses. Synaptech shall refer to Synaptech, Inc.

J. Plaintiffs object to these interrogatories to the extent they call for the collective knowledge and collective answer of separate entities.

K. Plaintiffs object to the interrogatories to the extent that they seek to impose an obligation on Plaintiffs to locate, obtain, and produce documents and things that are in the public domain, and therefore, are equally accessible to Defendants.

### **Responses**

In addition to the foregoing General Objections, which are incorporated into the following responses as if fully set forth in each response, Plaintiffs respond to the interrogatories as follows:

#### **Interrogatory No. 1:**

Provide a claim chart setting forth Janssen’s construction of each of the claims of the ‘318 patent, including a detailed explanation of Janssen’s asserted construction for these patent claims, and identifying the three (3) persons at Janssen with the most knowledge concerning Janssen’s asserted claim construction.

#### **Response:**

In addition to the foregoing General Objections, Plaintiffs object to this interrogatory as premature. Plaintiffs also object to the portion of the interrogatory calling for the identification of the three “persons at Janssen with the most knowledge” as improperly intruding into matters covered by the attorney-client privilege and work product doctrine. Subject to and without

waving this or any of the other foregoing objections, Plaintiffs will supplement their answer to this interrogatory and will provide Plaintiffs' proposed claim construction to Defendants upon the close of expert discovery.

**Interrogatory No. 2:**

Provide a claim chart for each claim of the '318 patent that Janssen asserts is or would be infringed by the products in Mylan's ANDA and/or the manufacture, use, sale, offer for sale, or importation of the products in Mylan's ANDA, with that chart including, but not limited to, a detailed explanation as to why each element of each claim is present in Mylan's ANDA and/or the products in Mylan's ANDA; a statement as to whether such alleged infringement is literal or under the doctrine of equivalents; a statement as to whether Janssen believes that claim would be infringed under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c); and the identity of the three (3) persons at Janssen with the most knowledge concerning such infringement claims.

**Response:**

In addition to the foregoing General Objections, Plaintiffs object to this interrogatory as premature as Plaintiffs have not yet had the opportunity to conduct fact or expert discovery. Plaintiffs also object to the portion of the interrogatory calling for the identification of the three "persons at Janssen with the most knowledge" as improperly intruding into matters covered by the attorney-client privilege and work product doctrine. Subject to and without waiving this or any of the other foregoing objections, Plaintiffs anticipate that they will assert that Defendants infringe claims 1 and 4 of the '318 patent; discovery and other fact development in the case may result in the assertion of infringement of other claims. Plaintiffs anticipate that they will supplement their answer to this interrogatory during the course of discovery.

**Interrogatory No. 3:**

Identify the dates on which the inventions allegedly disclosed in the '318 patent were first conceived, and for each date, identify with particularity the documentary evidence supporting that date (including, but not limited to, all laboratory notebooks where the alleged conception and/or invention is recorded) and all persons with any knowledge relating to that date (including, but not limited to, the individuals who allegedly conceived of the inventions claimed).

**Response:**

In addition to the foregoing General Objections, Plaintiffs object to this interrogatory as premature as Plaintiffs have not yet had the opportunity to conduct fact or expert discovery. Subject to and without waiving this or any of the other foregoing objections, Plaintiffs state that the named inventor of the '318 patent, Dr. Bonnie Davis, first considered using galantamine for the treatment of Alzheimer's disease in the late Summer/early Fall of 1978. She continued to study the properties of galantamine and the treatment of Alzheimer's disease during the succeeding years and filed her first patent application in January 1986. Plaintiffs will supplement this answer and identify documents concerning the conception and reduction to practice of the invention following the production of documents in the course of fact discovery.

**Interrogatory No. 4:**

Identify the dates on which the inventions allegedly disclosed in the '318 patent were reduced to practice, including any acts of diligence, and for each date, identify with particularity the documentary evidence supporting that date (including, but not limited to, all laboratory notebooks where the alleged reduction to practice and/or invention is recorded) and all persons with any knowledge relating to that date (including, but not limited to, the individuals who allegedly reduced to practice or assisted in the reduction to practice of the invention claimed).

**Response:**

In addition to the foregoing General Objections, Plaintiffs object to this interrogatory as premature as Plaintiffs have not yet had the opportunity to conduct fact or expert discovery.

Plaintiffs additionally object to the portion of the interrogatory that calls for Plaintiffs to “identify with particularity the documentary evidence supporting that date” as documents have not yet been produced in the case. Plaintiffs further object to this interrogatory as burdensome to answer in the form of a response to an interrogatory at this stage of the proceedings. Subject to and without waiving this or any of the other foregoing objections, Plaintiffs refer Defendants to Plaintiffs’ answer to Interrogatory #3.

**Interrogatory No. 5:**

Describe the circumstances, including the dates, in which the subject matter claimed in the ‘318 patent was first offered for sale, first described in a printed publication anywhere in the world, and first publicly used in the United States.

**Response:**

In addition to the foregoing General Objections, Plaintiffs object to this interrogatory as premature as Plaintiffs have not yet had the opportunity to conduct fact or expert discovery. Plaintiffs further object to this interrogatory as burdensome to answer in the form of a response to an interrogatory at this stage of the proceedings. Subject to and without waiving this or any of the other foregoing objections, Plaintiffs state that the subject matter of the ‘318 patent was first described in a printed publication when the ‘318 patent was published and first offered for sale and in public use in the United States following FDA approval of NDA 21-189 on Feb. 28, 2001.

**Interrogatory No. 6:**

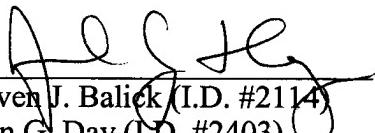
For all claims in the ‘318 patent that are being asserted against Mylan, identify whether Janssen intends to raise any assertion of secondary considerations in connection with any allegation that such claims are invalid for obviousness, and if so, identify, the specific secondary considerations on which Janssen intends to rely (i.e., commercial success, long felt need, failure by others), all documents supporting Janssen’s secondary consideration assertions (including but

not limited to, in the case of commercial success, proof of nexus, profit margins, marketing expenditures and the like), and the three (3) persons at Janssen most knowledgeable of such considerations and documents.

**Response:**

In addition to the foregoing General Objections, Plaintiffs object to this interrogatory as premature, vague, and unduly burdensome to call for all documents supporting Janssen's objective consideration assertions. Plaintiffs also object to the portion of the interrogatory calling for the identification of the three "persons at Janssen with the most knowledge" as improperly intruding into matters covered by the attorney-client privilege and work product doctrine. Plaintiffs will identify knowledgeable individuals in their Rule 26 initial disclosures. Subject to and without waiving this or any of the other foregoing objections, Plaintiffs state that they do intend to assert the objective considerations of non-obviousness in support of the validity of the '318 patent.

ASHBY & GEDDES



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Dated: October 12, 2005  
162335.1

**CERTIFICATE OF SERVICE**

I hereby certify that on the 12<sup>th</sup> day of October, 2005, the attached **PLAINTIFFS JANSSEN PHARMACEUTICA N.V.'S, JANSSEN, L.P.'S, AND SYNAPTECH, INC.'S OBJECTIONS AND RESPONSES TO DEFENDANTS MYLAN PHARMACEUTICALS INC.'S AND MYLAN LABORATORIES INC.'S FIRST SET OF INTERROGATORIES TO PLAINTIFFS (Nos. 1-6)** was served upon the below-named counsel of record at the address and in the manner indicated:

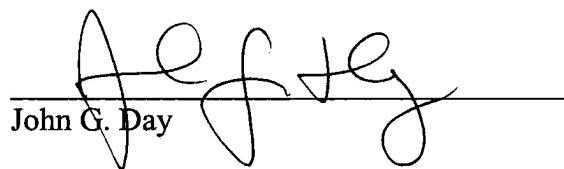
Mary B. Matterer, Esquire  
Morris James Hitchens & Williams LLP  
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HAND DELIVERY

William A. Rakoczy, Esquire  
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VIA FEDERAL EXPRESS

John G. Day



*In re: ‘318 Patent Infringement Litigation,  
C.A. No. 05-356 (KAJ) (consolidated) (D. Del.)*

**EXHIBIT D  
to Mylan’s 2/6/06 Letter to Court:**

Janssen Pharmaceutica N.V.’s Responses  
to Mylan’s First Request for Production

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V., )  
JANSSEN, L.P., and )  
SYNAPTECH, INC., )  
Plaintiffs/Counterclaim-Defendants, )  
v. ) Civ. Action No. 05-371-KAJ  
MYLAN PHARMACEUTICALS INC. )  
and MYLAN LABORATORIES INC., )  
Defendants/Counterclaim-Plaintiffs. )

**PLAINTIFF JANSSEN PHARMACEUTICA N.V.'S OBJECTIONS AND RESPONSES  
TO DEFENDANTS MYLAN PHARMACEUTICAL INC.'S AND MYLAN  
LABORATORIES INC.'S FIRST REQUEST  
FOR PRODUCTION OF DOCUMENTS (Nos. 1-22)**

Pursuant to Rule 34 of the Federal Rules of Civil Procedure, Plaintiff Janssen Pharmaceutica N.V. ("Janssen" or "Plaintiff") objects and responds to Defendants Mylan Pharmaceutical Inc.'s and Mylan Laboratories Inc.'s (collectively, "Mylan" or "Defendants") First Request for Production of Documents (Nos. 1-22) ("the document requests") as follows:

**General Objections**

A. Janssen objects to each of Defendants' document requests to the extent it seeks production of documents that are (i) subject to the attorney-client privilege; (ii) subject to attorney work product immunity; and/or (iii) subject to any other privilege. Janssen hereby claims such privileges and immunities to the extent implicated by each document request, and excludes privileged and protected information from its responses. Any disclosure of such privileged or immunized information is inadvertent and is not intended to waive those privileges and immunities.

B. Janssen objects to the document requests on the grounds and to the extent that they are overbroad and unduly burdensome. Janssen will conduct a reasonable search, limited to those locations and files where Janssen deems it reasonably likely that responsive documents will be found, for documents responsive to those portions of the document requests to which Janssen does not object.

C. Janssen objects to the document requests on the grounds and to the extent that they call for the provision of information that is not relevant to the subject matter of the pending action or that is not reasonably calculated to lead to the discovery of admissible evidence.

D. Janssen objects to the document requests, and to the Instructions and Definitions therein, on the grounds and to the extent that they purport to impose any obligation on Janssen that is beyond the scope of Rules 26 and 34 of the Federal Rules of Civil Procedure or other applicable law.

E. Janssen objects to the document requests to the extent that it purports to impose any obligation on Janssen that is beyond the scope of Rule 26(b)(5) of the Federal Rules of Civil Procedure or other applicable law.

F. Janssen objects to the document requests on the grounds and to the extent that they purport to require Janssen to search for and produce, or to identify, documents that are not in Janssen's possession, custody, or control.

G. Janssen's written responses and production of documents are based on information presently available to and located by Janssen and its attorneys. As Janssen has not completed its investigation of the facts relating to this case, its discovery in this action, or its

preparation for trial, Janssen's written responses and production of documents are made without prejudice to its right to supplement or amend its written responses and production of documents and to present evidence discovered hereafter at trial.

H. Janssen objects to the document requests to the extent that they purport to require production of information subject to confidentiality requirements or expectations between Janssen and any third party.

I. Janssen's responses are provided without prejudice to Janssen's right to oppose the admissibility or use of any document produced by Janssen or any other party or third party in this case. Janssen's production of a document in response to these requests should not be taken as an admission concerning the document's authenticity, relevance, or admissibility. Further, any statement in these responses that Janssen will produce any non-privileged responsive documents that are discovered in a reasonable search of files within its possession, custody, or control should not be construed as an assertion that any such documents in fact exist; such a statement means only that Janssen will conduct a reasonable, good-faith search for any such documents and will produce any non-privileged responsive documents that are found.

Janssen reserves its right to require the return of any privileged document that may inadvertently be produced in response to these requests. Janssen also reserves its right to designate (or re-designate) any confidential document that may inadvertently be produced without the appropriate confidentiality designation.

J. Janssen's objections and responses to the document requests, including any production of documents, are not intended to waive or prejudice any objections Janssen may assert now or in the future, including, without limitation, objections as to the relevance of the

subject matter of any document request, or of the admissibility of any response or document or category of responses or documents at trial. Janssen expressly reserves any and all rights and privileges under the Federal Rules of Civil Procedure, the Federal Rules of Evidence and any other law or rule, and the failure to assert such rights and privileges or the inadvertent disclosure by Janssen of information protected by such rights or privileges shall not constitute a waiver thereof, either with respect to these responses or with respect to any future discovery responses or objections.

K. Plaintiffs object to the document requests to the extent that the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues.

L. Plaintiffs object to Defendants' definition of "you," "your," "Janssen," "Janssen Pharmaceutica N.V.," "Janssen, L.P.," and "Synaptech" as confusing, overly broad, and unduly burdensome. For purposes of these interrogatories, "you" and "your" shall refer to Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc., named Plaintiffs to this litigation. "Janssen" shall refer to the named Plaintiffs, Janssen Pharmaceutica, N.V. or Janssen, L.P., either collectively or individually, as specified in each of Plaintiffs' responses. Synaptech shall refer to Synaptech, Inc.

M. Plaintiffs object to the document requests to the extent that they seek to impose an obligation on Plaintiffs to locate, obtain, and produce documents and things that are in the public domain, and therefore, are equally accessible to Defendants.

**Specific Objections and Responses**

In addition to the foregoing General Objections, which are incorporated into the following responses as if fully set forth in each response, Janssen responds to each of the requests contained in the document requests as follows:

**Request No. 1:**

All documents, communications and things on which Janssen intends to rely at trial in connection with any of the allegations in the complaint filed in the Current Litigation.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request as premature. Janssen also objects to the extent that the Request calls for documents subject to the Federal Rule of Civil Procedure 26(b)(5) and attorney-client and work product privileges. Janssen will comply with its obligations under the Federal Rules of Civil Procedure, Delaware Local Rules, and orders of the Court to provide disclosure of trial exhibits. Plaintiffs anticipate that the exhibits will include, *inter alia*, the '318 patent and relevant portions of the Defendants' ANDA.

**Request No. 2**

All documents, communications and things referred to, relied upon, cited, or otherwise used to prepare any answer to any interrogatory or request to admit propounded by Mylan in the Current Litigation.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request on the grounds that it is overly broad, vague and ambiguous. Janssen further objects to this Request insofar as it calls for the production of documents that are protected by the attorney-client and

work product privileges. Subject to and without waiving this or any of the other foregoing objections, Janssen will produce to Mylan, or make available for inspection and copying, any non-privileged documents that Janssen cites in its Response to Mylan's Interrogatories or Requests for Admissions.

**Request No. 3**

All documents, communications, and things referred to or relied upon by Janssen in asserting any and all allegations in the complaint filed in the Current Litigation.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request to the extent that it calls for documents protected by the attorney-client and work product privileges. Janssen further objects to this Request as vague as to the phrase "relied upon." Subject to and without waiving this or any of the other foregoing objections, Janssen will produce to Mylan, or make available for inspection and copying, any non-privileged documents, communications, and things referred to in the complaint filed in the Current Litigation.

**Request No. 4:**

All documents surrounding the alleged invention of the '318 patent, including but not limited to:

- (a) all laboratory notebooks or other documents relating to or concerning the conception and/or reduction to practice of the alleged invention of the '318 patent.
- (b) documents relating to the identity of the individuals who allegedly conceived of, and/or reduced to practice or assisted in the reduction to practice of, the invention claimed;
- (c) documents related to the date(s) on which such alleged conception and/or reduction to practice occurred;
- (d) all inventor disclosure statements that were prepared;

(e) all documents relating to the decision to file and prosecute the '318 patent; and

(f) all documents and /or information that the named inventor of the '318 patent, including her representatives, considered in connection with the development of the invention allegedly disclosed in the '318 patent, and/or in connection with the prosecution of this patent, regardless of whether such documents or information was cited to the PTO.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this interrogatory as vague and unclear with respect to documents "surrounding" the invention disclosed in the '318 patent. Janssen also objects to Subparts (d), (e), and (f) of the Request to the extent that they request documents protected by the attorney-client and work product doctrines. Subject to and without waiving this or any of the other foregoing objections, Janssen will perform a reasonable search for documents relevant to the issues of conception, reduction to practice of the invention disclosed in the '318 patent, and/or the validity of the '318 patent, including objective considerations of non-obviousness, and will produce to Mylan, or make available for inspection and copying, any such non-privileged documents that Janssen finds.

**Request No. 5**

All license or other agreements, assignments, transfers or liens concerning the '318 patent.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request on the grounds that it is overly broad, and that it would be unnecessarily expensive and unduly burdensome to produce the requested documents. Janssen further objects to this Request because it seeks documents that are irrelevant and immaterial to the matters involved in this lawsuit and is not reasonably calculated to lead to the discovery of evidence that would be admissible herein.

Subject to and without waiving this or any of the other foregoing objections, Janssen will perform a reasonable search for and will produce to Mylan, or make available for inspection and copying, a copy of each and every license, assignment, transfer or lien concerning the '318 patent.

**Request No. 6:**

All documents supporting any assertions of secondary considerations of nonobviousness that Janssen intends to raise in the Current Litigation and/or any Related Litigation, including but not limited to, proof of nexus, profit margins, and marketing expenditures.

**Response:**

In addition to the foregoing General Objections, Plaintiff objects to this request as premature. Subject to and without waiving this or any of the other foregoing objections, Janssen will perform a reasonable search for the documents that are relevant to the issue of validity of the '318 patent, including objective considerations of non-obviousness that Janssen intends to raise in the current litigation, and will produce to Mylan, or make available for inspection and copying, any such non-privileged documents that Janssen finds.

**Request No. 7:**

All documents that Janssen contends show the commercial success of any Janssen galantamine product.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request as overly broad and not reasonably calculated to lead to the discovery of evidence that would be admissible herein. Subject to and without waiving this or any of the other foregoing objections, Janssen will perform a reasonable search for any documents relevant to the issue of validity of

the '318 patent, including objective considerations of non-obviousness that Janssen will assert in the current litigation, and will produce to Mylan, or make available for inspection and copying, any such non-privileged documents that Janssen finds.

**Request No. 8:**

All documents concerning or referring to competition for any sale of any Janssen galantamine product.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request as overly broad, vague as to the phrase "competition for any sale," and not reasonably calculated to lead to the discovery of evidence that would be admissible herein. Subject to and without waiving this or any of the other foregoing objections, Janssen will perform a reasonable search for any documents relevant to the issue of validity of the '318 patent, including objective considerations of non-obviousness that Janssen will assert in the current litigation, and will produce to Mylan, or make available for inspection and copying, any such non-privileged documents that Janssen finds.

**Request No. 9:**

All notes, memoranda, and other written records of communications (including "call notes") between Janssen and/or its agents and any managed care organization, pharmacy benefit manager, physician, nurse, pharmacist, and/or other medical or medical office personal concerning, referring to or relating to any galantamine product (including any Janssen galantamine product).

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request as overly broad and not reasonably calculated to lead to the discovery of evidence that would be admissible herein. Subject to and without waiving this or any of the other foregoing objections,

Janssen will perform a reasonable search for any documents relevant to the issue of validity of the '318 patent, including objective considerations of non-obviousness that Janssen will assert in the current litigation, and will produce to Mylan, or make available for inspection and copying, any such non-privileged documents that Janssen finds.

**Request No. 10:**

All documents and things concerning, referring to or relating to the market for drugs used for the treatment of mild to moderate dementia of the Alzheimer's type, including but not limited to, documents identifying all drugs used for the treatment of mild to moderate dementia of the Alzheimer's type.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request on the grounds that it is overly broad, vague and ambiguous, and that it would be unnecessarily expensive and unduly burdensome to produce the requested documents. Janssen further objects to this Request because it calls for documents that are irrelevant and immaterial to the matters involved in this lawsuit and is not reasonably calculated to lead to the discovery of evidence that would be admissible herein. Subject to and without waiving this or any of the other foregoing objections, Janssen will perform a reasonable search for any documents relevant to the issue of validity of the '318 patent, including objective considerations of non-obviousness that Janssen will assert in the current litigation, and will produce to Mylan, or make available for inspection and copying, any such non-privileged documents that Janssen finds.

**Request No. 11:**

All documents and things concerning, referring to or relating to data and/or other information showing the uses for which any galantamine product (including Synaptech's galantamine product) is prescribed, used, and/or taken, including, but not limited to National Drug and Therapeutic Index data for any galantamine product.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request as overly broad. Janssen further objects to this Request because it calls for the production of documents that are irrelevant and immaterial to the matters involved in this lawsuit and is not reasonably calculated to lead to the discovery of evidence that would be admissible herein. Subject to and without waiving this or any of the other foregoing objections, Janssen will perform a reasonable search for any documents relevant to the issue of validity of the '318 patent, including objective considerations of non-obviousness that Janssen will assert in the current litigation, and will produce to Mylan, or make available for inspection and copying, any such non-privileged documents that Janssen finds.

**Request No. 12:**

All documents and things concerning, referring to or relating to the marketing of any galantamine product (including any Janssen galantamine product), including, but not limited to:

- a) all manuals, presentations, and/or other materials provided to, and/or used to train, sales representatives;
- b) all market research materials (including but not limited to surveys conducted by or on behalf of Janssen, scripts used, and results obtained);
- c) all communications between or among any persons of Janssen 's corporate headquarters, persons in district or regional management, and sales representatives;
- d) all notes, handouts, slides, and other presentation materials used at any plan of action (POA), launch, and/or other meeting;
- e) all marketing plans and products forecasts; and
- f) all field bulletins from Janssen to its sale representatives.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request on the grounds that it is overly broad, vague and ambiguous, and that it would be unnecessarily expensive and unduly burdensome to produce the requested documents. Janssen further objects to this Request because it seeks the production of documents that are irrelevant and immaterial to the matters involved in this lawsuit and is not reasonably calculated to lead to the discovery of evidence that would be admissible herein. Subject to and without waiving this or any of the other foregoing objections, Janssen will perform a reasonable search for any documents relevant to the issue of validity of the '318 patent, including objective considerations of non-obviousness that Janssen will assert in the current litigation, and will produce to Mylan, or make available for inspection and copying, any such non-privileged documents that Janssen finds.

**Request No. 13:**

All marketing and/or sales materials concerning, referring to or relating to any product used for the treatment of mild to moderate dementia of the Alzheimer's type (including any Janssen galantamine product), including, but not limited to:

- a) all display booth panels;
- b) all detail pieces or aids used by and/or provided to sales representatives, including but not limited to, ad slicks, slim jims, flash cards, and shelf-talkers,
- c) all telemarketing scripts, tele-detailing scripts, selling scripts, dealing scripts and/or verbatims used by and/or provided to sales representatives;
- d) all materials provided to physicians, managed care organizations, pharmacy benefit managers, pharmacists, and/or consumers;
- e) all advertisements appearing in journals, magazines, and/or newspapers;
- f) all patient education materials; and
- g) all copies of articles published by third-parties (sometimes referred to as reprints) used by and/or provided to sale representatives.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request on the grounds that it is overly broad, vague and ambiguous, and that it would be unnecessarily expensive and unduly burdensome to produce the requested documents. Janssen further objects to this Request because it seeks the production of documents that are irrelevant and immaterial to the matters involved in this lawsuit and is not reasonably calculated to lead to the discovery of evidence that would be admissible herein. Subject to and without waiving this or any of the other foregoing objections, Janssen will perform a reasonable search for any documents relevant to the issue of validity of the '318 patent, including objective considerations of non-obviousness that Janssen will assert in the current litigation, and will produce to Mylan, or make available for inspection and copying, any such non-privileged documents that Janssen finds.

**Request No. 14:**

All agreements concerning the rights to market and/or sell galantamine in the United States.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request on the grounds that it is overly broad and unduly burdensome. Janssen further objects to this Request because it seeks documents that are irrelevant and immaterial to the matters involved in this lawsuit and is not reasonably calculated to lead to the discovery of evidence that would be admissible herein. Subject to and without waiving this or any of the other foregoing objections, Janssen refers Defendants to documents produced in response to document request #5 and will perform a reasonable search for any documents relevant to the issue of validity of the '318 patent, including objective considerations of non-obviousness that Janssen will assert in the

current litigation, and will produce to Mylan, or make available for inspection and copying, any such non-privileged documents that Janssen finds.

**Request No. 15:**

All documents and things concerning, referring to or relating to data and/or other information showing sales of and/or prescriptions for any galantamine product (including Janssen 's galantamine product), including but not limited to:

- a) National Drug and Therapeutic Index (NDTI) data;
- b) Xponent data and/or Xponenet PlanTrak data
- c) Formulary Focus data;
- d) IMS data;
- e) Scott-Levin data;
- f) Calls, Samples, and Details data;
- g) Integrated Promotional Services (IPS) data; and
- h) Early View data.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request on the grounds that it is overly broad, vague and ambiguous, and that it would be unnecessarily expensive and unduly burdensome to produce the requested documents. Janssen further objects to this Request because it seeks documents that are irrelevant and immaterial to the matters involved in this lawsuit and is not reasonably calculated to lead to the discovery of evidence that would be admissible herein. Subject to and without waiving this or any of the other foregoing objections, Janssen will perform a reasonable search for any documents relevant to the issue of validity of the '318 patent, including objective considerations of non-obviousness that Janssen

will assert in the current litigation, and will produce to Mylan, or make available for inspection and copying, any such non-privileged documents that Janssen finds.

**Request No. 16:**

All documents that Janssen has produced or provided to any party, expert, consultant, or any third-party, relating to or concerning the Current Litigation and/or any Related Litigation concerning galantamine.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this request on the grounds that it is overly broad and unduly burdensome. Janssen further objects to this Request because it seeks documents that are irrelevant and immaterial to the matters involved in this lawsuit and is not reasonably calculated to lead to the discovery of evidence that would be admissible herein. Janssen objects that the Request includes documents subject to Federal Rule of Civil Procedure 26(b)(5) and attorney-client and work product privileges.

**Request No. 17:**

All documents that any party, expert, consultant, or any other third-party has drafted or otherwise prepared on behalf of Janssen and/or Janssen's attorneys and/or agents (including all drafts) related to or concerning the Current Litigation, and Related Litigation and any other U.S. or foreign litigation relating to or concerning galantamine.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this request on the grounds that it is overly broad and unduly burdensome. Janssen further objects to this Request because it seeks documents that are irrelevant and immaterial to the matters involved in this lawsuit and is not reasonably calculated to lead to the discovery of evidence that would be

admissible herein. Janssen objects that the Request includes documents subject to Federal Rule of Civil Procedure 26(b)(5) and attorney-client and work product privileges.

**Request No. 18:**

Any and all communications between or among Janssen L.P., Janssen Pharmaceutica and/or Synaptech relating to or concerning:

- a) the '318 patent;
- b) the Current Litigation;
- c) any Related Litigation;
- d) the alleged invention of the '318 patent;
- e) the prosecution of the '318 patent;
- f) any ANDA referencing NDA No. 21-169; and
- g) any notification received under 21 U.S. C. § 355 (j) referencing NDA. No. 21-169.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request on the grounds that it is overly broad, and that it would be unnecessarily expensive and unduly burdensome to produce the requested documents, which span nearly ten years time. Janssen also objects to this request as seeking highly proprietary information. Janssen further objects to this Request because it calls for the production of documents that are not reasonably calculated to lead to the discovery of evidence that would be admissible herein. Janssen also objects to the extent that the request covers documents subject to the attorney-client, joint defense, and work product privileges. Subject to and without waiving this or any of the other foregoing objections, Janssen will perform a reasonable search for any documents relevant to the issue of validity of

the '318 patent, including objective considerations of non-obviousness that Janssen will assert in the current litigation, and a copy of each and every Paragraph IV notification received pursuant to 21 U.S.C. § 355(j) referencing NDA No. 21-169.

**Request No. 19:**

Any and all notifications received under 21 U.S.C. § 355(j) referencing NDA No. 21-169 and all documents relating to or concerning all such notifications.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this request on the grounds that it is overly broad, vague, and unduly burdensome. Janssen further objects to this Request because it seeks documents that are irrelevant and immaterial to the matters involved in this lawsuit and is not reasonably calculated to lead to the discovery of evidence that would be admissible herein as the request calls for “all documents relating to or concerning all” notifications. Janssen also objects to this request as seeking highly proprietary information of Defendants’ competitors which is protected by confidentiality agreements. Subject to and without waiving any of the other foregoing General Objections, Janssen will perform a reasonable search for the documents identified in the document request, and will produce to Mylan, or make available for inspection and copying, a copy of each and every Paragraph IV notification received pursuant to 21 U.S.C. § 355(j) referencing NDA No. 21-169.

**Request No. 20:**

Any and all English language translations of any foreign-language documents requested in Mylan’s document production requests.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this request on the grounds that it seeks attorney work product and attorney-client communication. Janssen further objects to this request on the grounds that it would be unduly burdensome and would interfere with the conduct of litigation. Janssen interprets this request as calling for translations that were in the custody of Janssen prior to the anticipation of or preparation for litigation. Subject to and without waiving this or any of the other foregoing objections, Janssen will perform a reasonable search for and will produce to Defendants, or make available for inspection and copying, non-privileged English translations of foreign-language documents produced in response to Defendants' document requests that were in Janssen's custody prior to the anticipation of or preparation for litigation, to the extent such documents exist.

**Request No. 21:**

All documents concerning any of Janssen's policies and procedures for making, distributing, storing, retaining and/or destroying documents and records.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request on the grounds that it is overly broad as to time and scope, and that it would be unnecessarily expensive and unduly burdensome to produce the requested documents. Janssen further objects to this Request because it is not reasonably calculated to lead to the discovery of evidence that would be admissible herein. Subject to and without waiving this or any of the other foregoing objections, Janssen will perform a reasonable search for and will produce to Mylan, or make available for inspection and copying, documents, to the extent that they exist, that are sufficient to show Janssen's practices and policies regarding document retention.

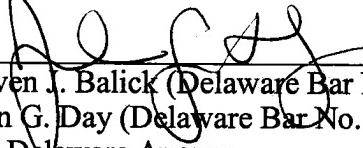
**Request No. 22:**

All documents and things depicting or otherwise evidencing Janssen's organizational structure as a company (e.g., organizational charts) from at least January 1, 1980 to the present.

**Response:**

In addition to the foregoing General Objections, Janssen objects to this Request on the grounds that it is vague and overly broad as to time and scope, and that it would be unnecessarily expensive and unduly burdensome to produce all documents depicting or evidencing Janssen's organizational structure. Janssen further objects to this Request because it is not reasonably calculated to lead to the discovery of evidence that would be admissible herein. Subject to and without waiving this or any of the other foregoing objections, Janssen will perform a reasonable search for and will produce to Mylan, or make available for inspection and copying, documents, to the extent that they exist, that are sufficient to show Janssen's organizational structure.

ASHBY & GEDDES



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DATED: October 12, 2005

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**CERTIFICATE OF SERVICE**

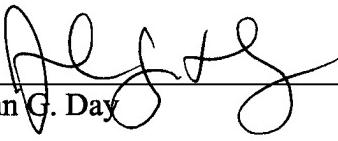
I hereby certify that on the 12<sup>th</sup> day of October, 2005, **PLAINTIFF JANSSEN PHARMACEUTICA N.V'S OBJECTIONS AND RESPONSES TO DEFENDANTS MYLAN PHARMACEUTICAL INC.'S AND MYLAN LABORATORIES INC.'S FIRST REQUEST FOR PRODUCTION OF DOCUMENTS (Nos. 1-22)** was served upon the following counsel of record at the address and in the manner indicated:

Mary B. Matterer, Esquire  
Morris James Hitchens & Williams LLP  
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VIA FEDERAL EXPRESS

  
John G. Day